EXHIBIT 2

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax:(973) 331-4969	03/18/2008 - 05/20/2008* FEI NUMBER 2244683
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
TO: Robert Wessman, CEO	
FIRM NAME Actavis Totowa LLC	STREET ADDRESS 990 Riverview Drive
CITY, STATE, ZIP CODE, COUNTRY Totowa, NJ 07512	TYPE ESTABLISHMENT INSPECTED Pharmaceutical Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

Quality System

OBSERVATION 1

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

The Quality Unit routinely failed to document, investigate and address product quality issues at the time of occurrence including in-process, finished product and stability out of specification analytical results. There is no assurance that the Quality Unit has the procedures, personnel, or systems to adequately evaluate the quality or validation status of the approximately [redacted] ANDA/NDA products and [redacted] non-application prescription products that they can currently manufacture and release to the market. The impact on finished product quality on the marketplace was not evaluated despite the confirmed out of specification results for at least [redacted] different marketed prescription products evaluated.

OBSERVATION 2

Drug products failing to meet established specifications and quality control criteria are not rejected.

Specifically,

a. During the packaging of Digoxin Tablets 0.125mg, lot# 70924A1, [redacted] double thick tablets were observed. Quality Assurance approved a 100% visual inspection of the [redacted] million tablet lot which resulted in an additional [redacted] double thick tablets. Although Quality Assurance was aware of the "double thick" tablet findings, the batch was then released based on AQL sampling which included visual inspection of [redacted] tablets. No additional thickness testing or analytical evaluation of the double thick tablets was conducted. No root cause was determined for the

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defect; however the lot was released to the market by the Quality Unit on 1/28/08 following the visual inspection. There was no documented evaluation of the approximately [redacted] lots that remained on the market at the time of inspection.

b. Pentazocine and Naloxone Hydrochlorides Tablets, USP, 50mg (base)/0.5mg (base) were manufactured with an overage of approximately 9% Naloxone Hydrochloride. The master batch record, "incorrectly corrected" the moisture content for the Naloxone HCl Dihydrate which led to the overage for batches manufactured from 9/8/05 until 3/25/08. Additionally, the laboratory practice was to dry the in-house standard for Naloxone HCl Dihydrate, however the method did not correct for drying the standard so the analysis did not reveal the overage. The Quality Assurance investigation was incomplete at the time of inspection despite the known manufacturing overage. There was no documented evaluation of the approximately [redacted] batches that remained on the market at the time of inspection.

OBSERVATION 3

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, the following products do not meet finished product or stability specifications throughout the products marketed expiry:

a. Out of specification assay results for Codeine Phosphate at the 12-month [redacted] and 18-month [redacted] stability stations were obtained on 8/21/07 and 1/16/08, respectively for Carisoprodol, Aspirin and Codeine Phosphate 200mg/325mg/16mg Tablets, lot# 60484A1, an annual stability lot. [redacted] retention samples were also out of specification for assay of Codeine Phosphate or Carisoprodol for lot#s 51044A1, 60121A1, 61024A1 and 5136A1. Although QA investigation 07-042, (initiated 7/20/07 and approved 11/9/07), revealed a manufacturing problem resulting in variability of the tablet bilayers for lot# 70484A, [redacted] the QA investigations for the stability out of specification results were not completed. There was no evaluation of the approximately [redacted] batches on the market at the time of inspection and no evaluation of other bilayer products.

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b. An out of specification assay value for Phentermine HCl [redacted] was obtained on 7/25/07 at the 24-month [redacted] stability time point for Phentermine HCl Capsules, 30 mg, lot# 5436A1, an annual stability lot. QA Investigation 07-066 concludes, "No other batches are impacted by this stability failure." A second stability out of specification assay result, [redacted] was obtained on 12/3/07 at the [redacted] RH stability time point for Phentermine HCl Capsules, 30mg, lot# 5704AQ. There was no evaluation of the approximately 16 batches on the market at the time of inspection.

c. Out of specification assay and impurity results were obtained on 11/13/07 for Hydrocodone Bitartrate and Homatropine Methylbromide Tablets 5mg/1.5mg, lot# 5683A1, at the [redacted] stability time point, [redacted] Homatropine HBr impurity result: [redacted] unknown impurity [redacted] Out of specification impurity results were also obtained on 12/26/07 during the testing of Hydrocodone Bitartrate and Homatropine Methylbromide Tablets 5mg/1.5mg, lot# 60437A1, an annual stability lot, at the [redacted] stability time point, [redacted] The Quality Assurance investigations were not completed and there was no evaluation of the 17 batches remaining on the market at the time of inspection.

d. Out of specification assay results were obtained on 12/4/07 for Amantadine Hydrochloride Capsules, USP, 100mg, lot# 60324A1, at the [redacted] stability time point [redacted] They were confirmed by re-measurement and retest; however the laboratory and Quality Assurance investigations were not completed and approved. No evaluation of the [redacted] batches remaining on the market had been made at the time of the inspection.

e. On 2/8/08 and 2/27/08, the 2006 and 2007 annual stability batches were out of specification for the known degradant 2,6 dichlorophenylacetic acid during the testing of Guanfacine Tablets USP, 1mg and 2mg. The product has a [redacted] month expiry for both strengths. There was no completed QA investigation and no evaluation of the approximately [redacted] batches of [redacted] batches of 2mg Guanfacine Tablets, USP that were on the market at the time of inspection.

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TYPE ESTABLISHMENT INSPECTED
Pharmaceutical Manufacturer

Packaged stability lot number (package size)	Strength	% 2,6 dichlorophenylacetic acid	Specification (%)	Stability Station 25°C/60%RH	Date of OOS
[redacted]					

f. On 1/4/08, an out of specification stability result was received for the known degradation product, Mirtazapine N-oxide (MTZNO), during the testing of Mirtazipine Orally Disintegrating Tablets, 15 mg Lot 60794A1 at the [redacted] stability time point [redacted] On 2/26/08, a second set of out of specification results for MTZNO was obtained during the testing of Mirtazipine Orally Disintegrating Tablets, 15 mg and 30 mg stability lot#s: 70279A1 (15 mg 9-month) [redacted] and 70421A1 (30 mg 6-month) [redacted] There was no completed QA investigation and no evaluation of the approximately [redacted] batches of 15mg and [redacted] batches of 30mg Mirtazapine Orally Disintegrating Tablets remaining on the market at the time of the inspection.

g. Out of specification results for a known impurity, methoxysulphamide, [redacted] were obtained for Glyburide (micronized) Tablets, 1.5mg, lot#60164A1 at the [redacted] stability time point on 10/3/07. The Quality Assurance Director in QA investigation 07-081, indicated that the only other batch on the market, 70200A1, (a stability batch), is [redacted] however; in the same report, it notes, [redacted] Out of specification stability results for the known impurity, methoxysulphamide, [redacted] were again obtained on 3/26/08 for Glyburide (micronized) Tablets, 3.0mg, lot# 60170A1 and 60170AQ; respectively at the [redacted] The Quality Assurance investigation remains incomplete. The impact of the out of specification stability results on the approximately [redacted] batches on the market at the time of inspection [redacted] was not evaluated.

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h. Out of specification assay results were obtained for Chlordiazepoxide [redacted] for Chlordiazepoxide and Clidinium Bromide Capsules 5mg/2.5mg, lot# 5553A3 (100's) on 8/3/07 at the [redacted] The lot has a 36 month expiry. A degradant was observed during assay testing but was not quantified. There are no impurity specifications for the product on stability. A retention sample that was not maintained at [redacted] was used to retest the batch and was in specification, however the Quality Unit approved a protocol to test additional retention samples at expiry on 10/10/07, which resulted in three additional out of specification assay result for Chlordiazepoxide at 36 months; [redacted] Approximately [redacted] batches with 36 month expiry and 28 batches with 24 month expiry remained on the market at the time of inspection.

i. Out of specification (low) assay results for Folic Acid were obtained for the prescription vitamin Multiret Folic Tablets 500mg, lot# 70607A1 (blister pack) at the [redacted] stability time point on 1/8/08 [redacted] Out of specification assay results for Folic Acid were also obtained for lot# 70065A1 (blister pack) at the [redacted] RH stability time point on 2/26/08 [redacted] There was no completed QA investigation and no evaluation of the approximately [redacted] batches on the market at the time of inspection.

j. Out of specification (high) assay results for Thiamin Mononitrate were obtained for the pediatric prescription vitamin Multi Vita Bets with 1.0 mg Fluoride and Iron Chewable Tablets, lot# 70602A1 (100's) at the [redacted] stability time point on 11/22/07 [redacted] Investigation OOSN# 07-155 revealed that a calculation error in the analytical method occurred in which test results were calculated and reported as Thiamin Mononitrate; however the label claim was for Thiamin. Recalculation resulted in assay results within specification for stability batch 70602A1. Recalculations were not conducted until approximately [redacted] months later for [redacted] formulations of Multi Vita Bets containing Thiamin to evaluate the impact of the error. [redacted] finished product lots, (Multi Vita Bets, 0.5mg F and Fe Chewable Tablets, lot# 60642A, 61093A, Multi Vita Bets, with 1.0mg F Tablets 60345A, Multi Vita Bets with 0.25mg F Chewable Tablets 60337A), and four stability lots, (Multi Vita Bets with 0.25mg F Chewable Tablets 60226AQ, Mutli Vita Bets with 0.5mg F Tablets 60259AQ, Multi Vita Bets, with 1.0mg F Tablets 60205A1, 60205A2), were out of specification (low) by recalculation for Thiamin. The remaining [redacted] prescription vitamins containing Thiamin had not been evaluated at the time of inspection.

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k. Out of specification (low) assay results for Acetaminophen and Dichloralphenazone were obtained for Amidrine Capsules, lot# 50638A1, an annual stability lot, at the [redacted] RH stability time point, [redacted] In a repeat test conducted by a second analyst, the Acetaminophen and Dichloralphenazone results were within specification but "borderline"; however the assay results of the third active ingredient, Isometheptene Mucate were out of specification [redacted] There was no completed QA investigation and no evaluation of the approximately [redacted] lots on the market

OBSERVATION 4

Determinations of conformance to appropriate written specifications for acceptance are deficient for in-process materials.

Specifically,

a. Although three out of specification results were obtained for blend uniformity at the "Right-Top" sample location for Digoxin Tablets 0.125 mg, lot#s 70148A (OOSN07-016), 70207A (OOSN07-022), and 70770A (OOSN07-116) on 2/20/07, 3/14/07 and 9/29/07; no manufacturing investigations were conducted. Additional samples were used to retest the blend and were reported. Lot# 70207A1 was released on 6/7/07 and lot# 70770A1 was released on 11/30/07 by the Quality Unit. Lot# 70148A was not released due to atypical content uniformity results.

b. Out of specification in-process results were obtained for friability of start-up and compression composite samples for Methenamine Mandelate Tablets 1.0g, lot# 70662A on 10/12/07. Despite the in-process out of specification results the batch was released to the market on 2/5/08 by the Quality Unit.

c. Although approximately [redacted] products were "temporarily discontinued" due to blend and/or content uniformity issues, there was no scientific rationale provided for the change of in process blend uniformity specifications from [redacted]

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d. Out of specification in-process blend uniformity testing of Oxycodone Tablets, 15mg, lot# 70164A was obtained on 3/3/07 [redacted]. Remeasurement confirmed the out of specification results [redacted]. No manufacturing investigation was conducted. A repeat test using a second set of blend samples resulted in an RSD of [redacted]. The batch was completed and released on 4/7/07.

OBSERVATION 5

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that components, in-process materials, and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

a. Analytical method transfers for each method from the Little Falls, NJ Quality Control Laboratory to the new Totowa, NJ Quality Control Laboratory were not conducted. Only two types of analytical methods, HPLC and GC were used to support the analytical transfer of approximately [redacted] in-process, finished product and stability methods. There were no analytical method transfers for such techniques as dissolution, atomic absorption, loss on drying, and blend testing.

b. There is no analytical evaluation of impurities on stability for approximately 48 prescription drug products such as Oxycodone HCl Tablets, 5mg, Phenazopyridine HCl Tablets, 200mg, Methenamine Mandelate Tablets, USP 1g, and Prenatal Plus with 27mg Iron Tablets to assure the strength, quality, and purity of the products throughout expiry.

c. A stability out-of-specification result for the Betaxolol Hydroxyethyl impurity [redacted] was observed during related substance testing of Betaxolol Tablets 10mg USP, lot# 60215A1 at the [redacted] time point. The impurity co-eluted with the solvent/placebo peak. Although it was determined that a new analytical method was required to adequately evaluate the product, the firm continued testing and releasing product to the marketplace. The Quality Assurance investigation was not completed at the time of inspection and approximately [redacted] lots remained on the market.

d. There is no assurance that all prescription vitamin products will maintain their labeled potency throughout expiry. Testing of all labeled ingredients on stability is not conducted.

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For example pediatric prescription multi-vitamins, Mutli Vita-Bets with 0.25mg, 0.5mg, and 1.0mg Fluoride and Iron Chewable Tablets and pre-natal prescription vitamins, Prenatal Plus with 27mg Iron Tablets are not analyzed for Iron on stability.

e. Out of specification or suspect test results for low assay were reported for Amantadine HCl Capsules, 100mg in OOSN 06-015, dated 11/16/06, STR 07-065, dated 7/3/07, OOSN 07-168, dated 12/4/07 and OOSN 07-183, dated 12/29/07. OOSN 07-168 resulted in a confirmed 18-month out of specification stability result for assay; however the other investigations attributed the low assay results to "extraction issues" with the GC method and manufacturing investigations were not conducted. Although the need for method remediation has been documented for the GC extraction method for assay of Amantadine HCl Capsules, 100mg since 11/16/06, corrective actions have not been implemented. QA Investigation 08-003 for the out of specification stability result obtained 12/4/07 remained in draft at the time of inspection.

OBSERVATION 6

Investigations of an unexplained discrepancy and a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy.

Specifically,

a. Although QA investigation 07-093, dated 1/25/08, for double thick Digoxin Tablets 0.125mg, lot# 70924A1, did not establish a root cause for the defective tablets, the investigation was not expanded to evaluate all finished product lots or strengths of Digoxin Tablets. At the time of inspection there were approximately 89 lots of Digoxin Tablets 0.125mg and 78 lots of Digoxin Tablets 0.250mg on the market within expiry.

b. Although a tablet capping issue was identified for Oxycodone Tablets 5mg, lot# 70976A on 12/14/07 and was attributed to damaged punches and dies in QA investigation 07-102, the investigation did not evaluate the impact on other finished product lots or strengths. Subsequently, four additional lots of Oxycodone HCl Tablets exhibited tablet capping, (30mg) lot# 80095A1, 80096A1, 80174A1; (15mg) 80165A1. QA investigations 08-032 and 08-042 for capping of Oxycodone HCl Tablets conclude that no other batches are impacted. Manufacturing of all strengths of Oxycodone Tablets continued despite the capping issues.

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c. Although an out of specification assay value [redacted] was obtained at the [redacted] stability testing time point for Phentermine HCl Capsules 30 mg, lot# 5436A1 on 7/25/07, QA Investigation 07-066 concludes, "No other batches are impacted by this stability failure." No root cause was identified and the investigation was not expanded to evaluate all finished product lots of Phentermine HCl Capsules. There are currently 23 lots of Phentermine HCl Capsules 30 mg on the market within expiry.

d. An error was identified in the formula calculation for Vitamin B1 (Thiamin) during the testing of the pediatric prescription vitamin, Multi Vita-Bets with 1.0 mg Fluoride, lot # 70602A1 [redacted] stability test point on 11/22/07. It resulted in Thiamin assay values being reported approximately [redacted] higher than the actual assay value for all lots. Although a planned deviation was written 1/17/08 to correct the calculation for 5 different pediatric multi-vitamin prescription formulations containing Vitamin B1 (Thiamin), the QA investigation 08-021 was not initiated until 2/14/08 and only evaluated other lots of Multi Vita-Bets. The investigation failed to evaluate all products which contain Vitamin B1 (Thiamin). In addition, the QA investigation, which remains incomplete, describes the impact of the deviation on batches as "Since these are non-ANDA products, and the assay results would fall below the specification, there is no significant impact as a result of this deviation."

OBSERVATION 7

An NDA-Field Alert Report was not submitted within three working days of receipt of information concerning a failure of one or more distributed batches of a drug to meet the specifications established for it in the application.

Specifically, field alert reports for the following products with confirmed stability out of specification results were not submitted within three working days of receipt of information:

a. Phentermine HCl Capsules, 30mg [redacted] stability lot# 5436A1 (1000 count), was out of specification for high assay on 7/25/07. Phentermine HCl Capsules, 30mg, [redacted] lot# 5704AQ (100 count), was out of specification for high assay on 11/30/07. The field alert report was filed 4/24/08, during the inspection.

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b. Glyburide (Micronized) Tablets USP 1.5mg, [redacted] lot# 60164A1 (100 count) was out of specification for a known impurity, methoxysulphamide, on 10/3/07. The field alert report was filed 11/29/07.

c. Pentazocine and Naloxone Hydrochloride Tablets USP 50mg/0.5mg [redacted] lot# 70053A2 was out of specification for assay of Naloxone on 1/3/08. The field alert report was filed 2/3/08.

d. Mirtazapine Orally Disintegrating Tablets, 15mg, [redacted] lot# 60794A1 (blister pack) was out of specification for a known degradant, MTZNO, on 1/4/08. The field alert report was filed 4/4/08, during the inspection.

OBSERVATION 8

Written records are not always made of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications.

Specifically, Quality Assurance investigations are not documented at the time of occurrence and are not completed in a timely manner as required by SOP 0033, Investigation of Deviations, dated 11/3/06. For example:

a. There is no completed Quality Assurance investigation into the formulation and analytical method calculation errors that led to the overage of approximately 9% Naloxone for all batches of Pentazocine and Naloxone Hydrochlorides Tablets, USP, 50mg (base)/0.5mg (base) from 9/8/05 until 3/25/08. The out of specification 9-month assay results for lot# 70053A2 were obtained 1/3/08 and the formulation error began 9/8/05.

b. There was no completed Quality Assurance investigation into the two out of specification assay results for Carisoprodol, Aspirin and Codeine Phosphate Tablets, 200/325/16mg, lot# 60484A1, obtained 8/21/07 and 1/16/08, respectively for the 12 and 18-month stability time points. A bilayer manufacturing problem was identified 8/28/07 in OOSN 07-067 regarding an out of specification acceptance value for Carisoprodol, [redacted] in Carisoprodol, Aspirin, and Codeine Phosphate Tablets, 200/325/16mg, lot# 70484A. Despite the known bilayer manufacturing problem and stability out of specification results, the Master Production Record was not placed on hold until 2/29/08 and the Master Production Record for another bilayer product, Carisoprodol/Asprin Tablets 200/325mg, was not placed on hold until 4/7/08, during the inspection.

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c. No QA investigation was initiated following the confirmed stability out of specification known impurity, MTZNO at the [redacted]r Mirtazapine Orally Disintegrating Tablets, 15mg, lot# 60794A1 on 1/4/08. [redacted] additional out of specification stability results were obtained for lot#s 70279A1 (9-month), 70420A2 (6-month), and Mirtazapine Orally Disintegrating Tablets, 30mg, lot# 70421A1 on 2/26/08 for the same known impurity. The QA investigation remained in draft during the inspection.

d. There was no completed Quality Assurance investigation into the [redacted] stability out of specification Folic Acid assay results for Multiret Folic 500 Tablets, lot#s 70607A1 and 70065A1 obtained 1/11/08 and 2/28/08, respectively.

e. There was no Quality Assurance investigation initiated for the discrepancy between the required stability time points as documented in the stability protocol versus the actual time points listed in the electronic stability program. The impact on other stability studies was not assessed. For example:

i. The 9-month and 18-month stability stations were not originally included in the electronic stability program for Buspirone HCl Tablets, 5mg, lot# 60502A2, 60502AQ, 70036A2, and 70036AQ. The time points were added on 10/30/07, approximately [redacted] for lot# 60502A2.

ii. The 18-month stability station was not originally included in the electronic stability program for Drixoral Cold and Allergy ER Tablets, Tablets Lot # 70085A (7-DRT-1) blister pack.

f. No QA investigation was initiated when an operator observed grease visibly trickling off of the tablet press during the compression of Oxycodone HCl USP Tablets, 5 mg, lot# 70761A1 compressed from 9/18/07-9/23/07. QA investigation 07-073 was subsequently initiated for the lot on 10/3/07 due to the presence of black spots on the tablets, observed during the packaging operation.

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	Elizabeth McCaffery	05/20/2008

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969	03/18/2008 - 05/20/2008* FEI NUMBER 2244683

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Robert Wessman, CEO

FIRM NAME	STREET ADDRESS
Actavis Totowa LLC	990 Riverview Drive
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Totowa, NJ 07512	Pharmaceutical Manufacturer

OBSERVATION 9

Written production and process control procedures are not followed in the execution of production and process control functions and documented at the time of performance.

Specifically,

a. [redacted] dated 11/3/06 requires completion of investigations within [redacted] working days. If an extension is needed, a memo to file describing the progress and the target completion date is required. Numerous Quality Assurance investigations remained open during the inspection including investigations of out of specification finished product and stability out of specification results such as Carisoprodol, Aspirin, and Codeine Phosphate Tablets, USP, lot# 60484A1 initiated 9/4/07, Guanfacine Tablets 2mg, lot#s 5393A2 and 5393A1, initiated 12/11/07. Extension memos were routinely written and approved by the Quality Unit with no justification or description of the investigation progress or potential impact on other product on the market.

b. [redacted] dated 7/26/07 does not clearly identify the steps to be taken or samples to be tested by each analyst in an investigation of out of specification or suspect test results. Although solutions are suggested for re-measurement, there is no requirement to evaluate the original tablet grind material when testing a tablet product. Additionally, manufacturing investigations are not initiated at that time of retesting.

c. [redacted], dated 10/31/07 requires the filing of a Field Alert within [redacted] working days after receipt of information (confirmed or unconfirmed) for such issues as stability failures or any other significant chemical, physical or other change in a distributed product. The procedure was not followed in that field alerts were not filed within three working days. For example: Phentermine HCl Capsules 30mg, lot# 5436A1 which was filed approximately 9 months after the out of specification stability result and Mirtazapine Orally Disintegrating Tablets, lot# 60794A1 which was filed approximately 3 months after the out of specification stability result.

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OBSERVATION 10

Changes to written procedures are not reviewed and approved by the quality control unit.

Specifically,

Changes are not all captured within the formal change control system. Changes that are documented in Work Orders are not reviewed and approved by the Quality Unit. In addition, documentation of justification for changes within the change control system is required by [redacted], but this justification is lacking in detail with respect to product quality. For example:

a. Work Order Forms, which are not reviewed and approved by the Quality Unit, are issued when transferring equipment from one facility to another and when equipment is not functioning properly. For example:

   i. The Quality Unit did not review and approve [redacted] issued on 12/27/07 and 2/12/08, respectively, to document the transfer of the [redacted] used for the production of Digoxin Tablets, from the Little Falls, NJ manufacturing facility to the Riverview, NJ manufacturing facility. No formal qualification was conducted following the movement of the blender from one site to another.

   ii. The Quality Unit did not review and approve [redacted] opened on 3/31/08, to document "the linear scale sensor on the [redacted] not working". A new sensor was ordered, but no evaluation for potential product impact was made. Vitaplex Tablets, batch# 80249A were manufactured on the equipment from 3/29/08-4/3/08. There is no notation of the work on the production record. Multiple formulations of pediatric prescription vitamins, Multi Vita Bets Tablets were also recently manufactured using the equipment.

   iii. The Quality Unit did not review and approve [redacted] opened on 4/4/08, to document [redacted] is not working properly". The main bearing was replaced due to this work order, but there was no evaluation for potential product impact. Cyclobenzaprine HCl Tablets, USP 5mg, batch# 80258A was coated 4/1/08-4/4/08 on this equipment and was used for such other products as Prenatal Plus with 27mg Iron Tablets, Dipyridamole Tablets, USP 75mg, and Mirtazapine Tablets, 30mg.

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b. The justification for making changes within the change control system is not documented or is incomplete. For example:

i No justification is included in [redacted] regarding a change in chromatographic column in the analysis of Betaxolol Tablets, USP 10 mg and 20 mg. This change involved the replacement of the chromatographic column used for Assay and Impurity testing. The use of the new column with the existing analytical method resulted in co-elution of chromatographic peaks during impurity testing.

ii Although [redacted], initiated on 3/17/08, was used to remove erroneous calculations which led to the overcharge of Naloxone in Pentazocine and Naloxone Hydrochlorides Tablets USP, 50mg/0.5mg, the justification for the change was not documented in the change control.

iii [redacted] was initiated on 2/20/08 in order to change the container and closure for Hydrocodone Bitartrate and Homatropine Methylbromide Tablets 5mg/1.5mg to address out-of-specification impurity results on stability; however the change control does not include the justification for the proposed change.

OBSERVATION 11

Drug product production and control records, are not reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.

Specifically,

Investigations of Deviation Reports require a review by Quality Assurance, an approval by Regulatory Affairs/Quality Compliance and an approval of product disposition by the Head of Quality Assurance. On multiple occasions, these three signatories were completed by the same individual. For example:

a. [redacted] regarding double thick [redacted] was signed by the Director of Quality Assurance under the sections designated for Quality Assurance, Regulatory Affairs/Quality Compliance and the Head of Quality Assurance.

b [redacted] egarding capped tablets observed during the packaging of Oxycodone Hydrochloride Tablets, USP 5 mg, lot # 70976A, was signed by the

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Director of Quality Assurance under the sections designated for Quality Assurance, Regulatory Affairs/Quality Compliance and the Head of Quality Assurance.

c. [redacted] regarding out of specification assay test results for Carisoprodol, Aspirin & Codeine Phosphate Tablets 200/325/16 mg, lot# 60484A1 at the 12-month 25°C/60%RH stability station was observed 8/21/07 and was signed by the Director of Quality Assurance on 3/7/08 under the sections designated for Quality Assurance and Regulatory Affairs/Quality Compliance. The section for Product Disposition to be signed by and the Head of Quality Assurance is currently not signed.

d. [redacted] regarding discoloration of Multi Vita-Bets with 1.0 mg Fluoride Tablets, lot #60061A1 at the 24-month 25°C/60%RH stability station was signed by the Senior Manager Quality & Investigation on 3/25/08 under the sections designated for Quality Assurance, Regulatory Affairs/Quality Compliance and the Head of Quality Assurance.

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* DATES OF INSPECTION:
03/18/2008(Tue), 03/19/2008(Wed), 03/20/2008(Thu), 03/24/2008(Mon), 03/25/2008(Tue), 03/26/2008(Wed), 03/27/2008(Thu), 04/01/2008(Tue), 04/02/2008(Wed), 04/03/2008(Thu), 04/07/2008(Mon), 04/08/2008(Tue), 04/09/2008(Wed), 04/14/2008(Mon), 04/15/2008(Tue), 04/16/2008(Wed), 04/17/2008(Thu), 04/22/2008(Tue), 04/23/2008(Wed), 04/29/2008(Tue), 05/02/2008(Fri), 05/07/2008(Wed), 05/08/2008(Thu), 05/13/2008(Tue), 05/14/2008(Wed), 05/20/2008(Tue)

FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

Erin D. McCaffery, Investigator

Kristy A. Zielny, Investigator

RELEASE

REVIEWED BY AZ 8/20/08
C.O. DATE

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